Detailed Action

The Amendments and Remarks filed 3/17/10 in response to the Office Action of 8/11/09 are acknowledged and have been entered.

Claims 25-28 have been added by Applicant.

Claims1, 5-10, 16-28 are pending.

Claims 6, 8, 10, and 16-18 have been withdrawn.

Claims 1, 5-9, 16, 20, 22, and 24 have been amended by Applicant.

Claims 1, 5, 7, 9, and 20-28 are currently under examination.

Inventorship

The first named inventor has been corrected to "Charles L. Sawyers".

Objections Withdrawn

The objection to the specification has been withdrawn.

Rejections Withdrawn

The rejections under 35 U.S.C. 112, second paragraph, have been withdrawn.

The rejection of claims 1 and 20-24 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement (for being inclusive of a genus of compounds which (1) decrease androgen receptor DNA levels, androgen receptor

mRNA levels, or androgen receptor protein levels and (2) inhibit the growth of hormone-refractory prostate cancer cells) is withdrawn.

The rejections under 35 U.S.C. 102(b) are withdrawn.

Response to Arguments

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 20-24 remain rejected and claims 5, 7, 9, and 25-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a **NEW MATTER** rejection.

Independent claims 1 and 5 recite methods of examining physiological effects of a compound on a cancer cell expressing exogenous wild-type androgen receptor polynucleotide wherein growth of said cell is "androgen-independent" or "nuclear receptor ligand-independent". Descriptions of methods of examining physiological effects of a compound on a cancer cell expressing exogenous wild-type androgen receptor polynucleotide wherein growth of said cell is "androgen-independent" or "nuclear receptor ligand-independent" are not found in the specification in such a way

as to reasonably convey to one skilled in the relevant art that the inventors, at the time the invention was filed, had possession of the claimed invention.

In the Reply of 3/17/10, Applicant states that paragraph [0005] indicates the terms "androgen independent" and "hormone refractory (HR)" are used interchangeably in the specification. Applicant indicates support for methods of examining physiological effects of a compound on a cancer cell expressing exogenous wild-type androgen receptor polynucleotide wherein growth of said cell is "androgen-independent" or "nuclear receptor ligand-independent" can be found at paragraphs [0010], [0011]-[0015], [0016]-[0018], and [0035]-[0040].

The amendments to the claims and the arguments found in the Reply of 3/17/10 have been carefully considered, but are not deemed persuasive. In regards to the statement that paragraph [0005] indicates the terms "androgen independent" and "hormone refractory (HR)" are used interchangeably in the specification, paragraph [0005] does not disclose the terms "androgen independent" and "hormone refractory (HR)" are used interchangeably in the specification. Further, [0042] clearly discloses differences between "androgen independent" and "hormone refractory (HR)" with the statement that "the widely used term "androgen-independent" may be a misleading description of HR prostate cancer".

In regards to the argument that paragraph [0010] provides support, paragraph [0010] does not disclose methods of examining physiological effects of a compound on a cancer cell expressing exogenous wild-type androgen receptor polynucleotide wherein growth of said cell is "androgen-independent" or "nuclear receptor ligand-

independent". Rather, paragraph [0010] states that the disclosure "includes assays for examining the effects of therapeutic compounds on mammalian cells such as androgen independent prostate cancer cells". Paragraph [0010] does not disclose methods of examining physiological effects of a compound on a cancer cell expressing exogenous wild-type androgen receptor polynucleotide wherein growth of said cell is "androgen-independent" or "nuclear receptor ligand-independent".

In regards to the argument that paragraphs [0011]-[0015] provide support, paragraphs [0011]-[0015] do not disclose methods of examining physiological effects of a compound on a cancer cell expressing exogenous wild-type androgen receptor polynucleotide wherein growth of said cell is "androgen-independent" or "nuclear receptor ligand-independent". Rather, paragraphs [0011]-[0015] disclose methods of examining physiological effects of a compound on a cancer cell expressing exogenous wild-type androgen receptor polynucleotide. Paragraphs [0011]-[0015] do not disclose methods of examining physiological effects of a compound on a cancer cell expressing exogenous wild-type androgen receptor polynucleotide wherein growth of said cell is "androgen-independent" or "nuclear receptor ligand-independent".

In regards to the argument that paragraphs [0016]-[0018] provide support, paragraphs [0016]-[0018] do not disclose methods of examining physiological effects of a compound on a cancer cell expressing exogenous wild-type androgen receptor polynucleotide wherein growth of said cell is "androgen-independent" or "nuclear receptor ligand-independent". Rather, paragraphs [0016]-[0018] disclose methods of treating hormone refractory prostate cancer in a patient. Paragraphs [0016]-[0018] do

not disclose methods of examining physiological effects of a compound on a cancer cell expressing exogenous wild-type androgen receptor polynucleotide wherein growth of said cell is "androgen-independent" or "nuclear receptor ligand-independent".

In regards to the argument that paragraphs [0035]-[0040] provide support, paragraphs [0035]-[0040] do not disclose methods of examining physiological effects of a compound on a cancer cell expressing exogenous wild-type androgen receptor polynucleotide wherein growth of said cell is "androgen-independent" or "nuclear receptor ligand-independent". Rather, paragraphs [0035]-[0040] disclose methods of examining expression in HS and HR cells, methods of examining physiological effects of a compound on a cancer cell expressing exogenous wild-type androgen receptor polynucleotide *wherein growth of said cell is responsive to synthetic antigen* (androgen dependent). Paragraphs [0035]-[0040] do not disclose methods of examining physiological effects of a compound on a cancer cell expressing exogenous wild-type androgen receptor polynucleotide wherein growth of said cell is "androgen-independent" or "nuclear receptor ligand-independent".

Summary

No claim is allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN E. AEDER whose telephone number is (571)272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean E Aeder/
Primary Examiner, Art Unit 1642